510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: March 12, 2014

1. Company and Correspondent making the submission:
   - Name: Sonomed Inc.
   - Address: 1979 Marcus Ave
     Lake Success, NY, 11798
     U.S.A.
   - Telephone: 516-354-0900
   - Fax: 516-354
   - Website: www.sonomed.com
   - Contact: Mr. Charles C. O'Neal, Quality Manager
   - E-mail: coneal@escalonmed.com

2. Device:
   - Trade/proprietary name: VuPad
   - 510(k) Number: K140199
   - Common Name: Diagnostic ultrasound system
   - Classification Name: System, imaging, pulsed echo, ultrasonic

3. Predicate Devices:
   - Manufacturer: Sonomed, Inc.
     Device: E-Z Scan 5500+ A-Scan / B-Scan System
     510(k) Number: K040668
   - Manufacturer: Sonomed, Inc.
     Device: VuMax System
     510(k) Number: K060626

4. Classification Names & Citations:
   - Classification: Class 2
   - Classification Code: 21CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic,

5. Description:

   The VuPad is a portable ultrasound biometric ruler intended for use in ophthalmic applications. The system allows for the measurement of several key ocular features including axial length (AXL), anterior chamber depth, and lens thickness while also aiding in the calculation of associated IOL power for implanted lenses.

   The device is used by coupling the probe / transducer to the eye either through direct contact or immersion methods. Available modes are biometric A-scan, B-scan, and UBM (high frequency B-scan).

   The A-scan mode of the system features a live A-scan trace with storage for up to five scans. There are five (auto/ manual) examination modes that use three different tissue velocities to calculate individual intraocular distances within the eye (ACD, Lens, and Vitreous). Other features include: post examination review of scans & measurement; five IOL formulas (six refractive and three post refractive) for lens power calculations; an immersion scanning capability for zero corneal compression of the eye while scanning and storage for up to five different user profiles.

The B-Scan mode produces a live, two-dimensional image to facilitate the identification and measurement of ocular pathologies in the posterior-chamber of the eye, particularly when view of the chamber is obscured, such as is the case with cataracts.

The VuPad is a stand-alone system that runs on a Windows 8 platform and may be networked (by the user) for interface with electronic medical records systems, printing, and other purposes. The system consists of the VuPad console, ultrasound probe(s) and transducer(s), and foot pedal.

6. Indications for Use:
   The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

7. Comparison with predicate device:
   Sonomed, Inc. believes that the technologies incorporated into the VuPad are substantially equivalent to those of the E-Z Scan 5500+ A-scan / B-scan system and the VuMax System.

   A summary listing of design characteristics that are shared between the VuPad and the established predicate devices is provided on the following pages.

   A summary listing of design characteristics that differ between the VuPad and the established predicate devices is also provided on the following pages.

Section 2 – 510(K) Summary

A summary listing of VuPad design characteristics that are the same as established predicate devices is provided below:

Parameter	VuPad (K140199)	EZScan AB5500+ (K040668)	VuMax (K060626)
Similarities			
Intended Use	The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.	The EZ Scan ultrasound system is a multi-purpose computer based ultrasonic diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.	The VuMAX ultrasound syst5em is a multi-purpose computer -based ultrasonic diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye.
Ultrasound Modes	Ophthalmic A and B Scans	Ophthalmic A and B Scans	Ophthalmic A and B Scans
Technology	Visualization by Ultrasound	Visualization by Ultrasound	Visualization by Ultrasound
General Method of Operation	Echoes converted to images on a screen. Measurement made by time delays	Echoes converted to images on a screen. Measurement made by time delays	Echoes converted to images on a screen. Measurement made by time delays
Digital System	Echoes converted into digital pulses, all operation carried out digitally	Echoes converted into digital pulses, all operation carried out digitally	Echoes converted into digital pulses, all operation carried out digitally
Ability To Make Measurements	Can make measurements using A-scan technology	Can make measurements using A-scan technology	Can make measurements using A-scan technology
Eye-transducer Interface	Sealed probes with scanning transducer behind ultrasound transparent membrane (10, 12.5, 20 MHz); and Stand-off or "nose-scone" separates exposed transducer from patient (35, 50 MHz)	Sealed probes with scanning transducer behind ultrasound transparent membrane (10 MHz)	Stand-off or "nose-scone" separates exposed transducer from patient (35, 50 MHz)
IOL Power Calculation	Various formulas available	Various formulas available	Not available
Method of generating A-Scans	Separate A-Scan transducer, A-scan measuring system	Separate A-Scan transducer, A-scan measuring system	Line traced on B-Scan, A-scan shown, caliper for measurement
Focus feature	Improves resolution by reducing transducer ringing by software	Not available.	Improves resolution by reducing transducer ringing by software
A-Scan Probe Design	Closed Fixed Single-Element with Internal Fixation Light	Closed Fixed Single-Element with Internal Fixation Light	N/A

Parameter	VuPad (K140199)	EZScan AB5500+ (K040668)	VuMax (K060626)
Similarities (cont.)			
A-Scan Transducer Frequency	10 MHz	10 MHz	N/A
A-Scan Available Probe Configurations	Solid Tip (for immersion scan) Soft-Touch (for direct contact scan)	Solid Tip (for immersion scan) Soft-Touch (for direct contact scan)	N/A
A-Scan Measurements	Anterior Chamber Depth Lens Thickness Axial Length Manual Measurements	Anterior Chamber Depth Lens Thickness Axial Length Manual Measurements	N/A
A-Scan Measurement Accuracy	±0.1 mm (clinical) ±0.02 mm (theoretical)	±0.1 mm (clinical) ±0.023 mm (theoretical)	N/A
A-Scan Measurement Range	18 - 40 mm	18 - 40 mm	N/A
A-Scan Measurement Modes	Automatic – Cataract Automatic – Dense Cataract Automatic – Aphakic Automatic – Pseduophakic Manual	Automatic – Cataract Automatic – Dense Cataract Automatic – Aphakic Automatic – Pseduophakic Manual	N/A
A-Scan IOL Formulas	Holladay Regression-II Theoretic-T Binkhorst Hoffer-Q Haigis Latkany Mypoic Post-Refractive Latkany Hyperoptic Post-Refractive Aramberri Double-K Post-Refractive	Holladay Regression-II Theoretic-T Binkhorst Hoffer-Q Haigis Latkany Mypoic Post-Refractive Latkany Hyperoptic Post-Refractive Aramberri Double-K Post-Refractive	N/A
A-Scan Tissue Velocity Constants	Anterior Chamber Lens Vitreous	Anterior Chamber Lens Vitreous	N/A
A-Scan User Constants	Personalized A-Constants Surgeon Factors	Personalized A-Constants Surgeon Factors	N/A
A-Scan Acoustic Output Global Maximum	$I_{SPTA.3}$ < 50 mW/cm^2 MI < 0.23	$I_{SPTA.3}$ < 50 mW/cm^2 MI < 0.23	N/A
B-Scan Probe Design	Sealed Pivoting Single-Element, and Open Pivoting Single-Element	Sealed Pivoting Single-Element Only	Open Pivoting Single-Element Only
B-Scan Lines per Scan	256	128 or 256	256
Selectable A-Scan Vector while in B-Scan mode	Yes	Yes	Yes

Parameter	VuPad (K140199)	EZScan AB5500+ (K040668)	VuMax (K060626)
Similarities (cont.)			
B-Scan Scan Display Controls	Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain	Fully adjustable time-varied gain (TVG), log gain, and exponential gain	Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain
B-Scan Video Clips	Capture and store 50-frame video clips	N/A	Capture and store 50-frame video clips

Section 2 – 510(K) Summary

A summary listing of VuPad design characteristics that differ from established predicate devices is provided below:

Parameter	VuPad	EZScan AB5500+ K040668	VuMax
Differences			
Hardware Configuration and Components	System consists of unit with integrated LCD touch screen, A-probe, sealed B-probe, open transducer water path B-probe, calibration cylinder, probe holder, and foot pedal	System consists of unit with integrated LCD touch screen, A-probe, sealed B-probe, calibration cylinder, probe holder, and foot pedal	Systems consists of tower PC with integrated ultrasound electronics, PC monitor, open transducer water path B-probe, keyboard, mouse, and foot pedal
Control Interface	Operator uses tablet PC with LCD touch screen and foot pedal switch to collect exam data.	Operator uses LCD touch screen and foot pedal switch to collect exam data.	Operator uses desktop computer control interface to collect exam data. Hardware includes monitor, keyboard, mouse, and foot pedal switch.
System Dimensions	13.3" x 8.0" x 2.0"	9.4" x 8.9" x 2.8"	Dimensions vary for multiple components
Display Screen	Integrated LCD Panel (10.1" diagonal wide-screen, 1920 x 1080 pixel resolution)	Integrated LCD Panel (5.25" x 3.4", 640x480)	PC Monitor (17" Diagonal, 1280 x 1024 pixel resolution)
Data Storage Location	Storage within software database with ability to recall patient exam records	Internal storage of a single patient exam (previous exam data overwritten when new exam initiated) Capability to export exam record to PC via serial connector for long-term storage	Storage within software database with ability to recall patient exam records
Printer	Any Windows-compatible printer (separate)	Sony UP-897MD video printer (separate)	Any Windows-compatible printer (separate)
A-Scan Measurement Accuracy	±0.1 mm (clinical) ±0.02 mm theoretical)	±0.1 mm (clinical) ±0.023 mm (theoretical)	N/A
B-Scan Transducer Frequencies	12.5 MHz, 20 MHz, 35 MHz, 50MHz	10MHz	35 MHz, 50MHz
B-Scan Transducer drive and receiver	Circuitry suitable for 12.5-50MHz	Circuitry suitable for 10MHz	Circuitry suitable for 10-50 MHz
B-Scan Axial Accuracy (Theoretical)	12.5 MHz: 0.2034 mm 35 or 50 MHz: 0.0146mm	10 MHz: 0.2088 mm	35 or 50 MHz: 0.0146mm

8. Conclusions:
   The goal in designing the VuPad system was to combine the primary features of two previously marketed predicate devices into a single self-contained package along with enhancements in ergonomics and utility that embody the current state of the industry.

   The core technologies incorporated into the VuPad are primarily based on two predicate devices that are currently legally marketed by Sonomed, Inc: the E-Z Scan 5500+ A-Scan / B-Scan system (K040668) and the VuMax System (K060626). The similarities in intended usage, method of application, and system capability between the VuPad and predicate devices are evidenced in the comparison tables provided herein.

   Both the E-Z Scan 5500+ A/B system and the VuPad system provide Operators with a combination of B-scan and A-scan ultrasound. The A-scan technology incorporated into the VuPad system is fundamentally identical to that currently in use by the E-Z Scan 5500+ A/B system.

   Similarly, the Ultrasound Biomicroscopy (UBM) capabilities of the VuPad System are fundamentally identical to that of the VuMAX. The VuPad utilizes the exact same models of 35Mhz and 50Mhz transducers as the VuMAX system to collect live B-scan images of the anterior segment of the eye. The intended usage and method of application for these transducers are the same for both systems.

   The VuPad also provides users with the additional option of using 12.5 MHz or 20 MHz B-scan transducers for enhanced B-Scan imaging of the posterior segment of the eye. The intended use and application of these transducers are exactly the same as the 10 MHz B-scan transducer provided for use with the previously cleared E-Z Scan AB5500+. The dual transducer frequencies made available with the VuPad system (12.5 MHz and 20 MHz) provide users with superior image resolution and greater exam flexibility while maintaining a comparable scanning depth when compared to the use of a single 10 MHz transducer.

   The differences in Hardware Configuration, Control Interface, System Dimensions, Display Screen, Data Storage Location, and Printing Capability evident in the VuPad system do not render the device substantially different from the predicate devices because they do not establish a new intended usage, nor do they significantly alter the core A-scan and B-scan scan technologies employed by the system. These variances in form factor and data presentation have been evaluated by Sonomed's Risk Management Team and shall be addressed and fully detailed within the Operator's Instruction Manual that shall accompany the system.

   In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification Sonomed, Inc. has concluded that the VuPad is safe and effective and substantially equivalent to predicate devices as described herein.

9. Safety, EMC and Performance Data:
   Electrical, mechanical, environments safety and performance testing according to standard IEC 60601-1, IEC 60601-2-37, and EN/IEC 60601-1-2(2001) are currently pending.

10. Sonomed Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 1, 2014

Sonomed, Inc.
% Mr. Charles O'Neal
Quality Manager
1979 Marcus Avenue, Suite 105C
LAKE SUCCESS NY 11042

Re: K140199
Trade/Device Name: VuPad
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: March 12, 2014
Received: March 20, 2014

Dear Mr. O'Neal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140199

Device Name
VuPad

Indications for Use *(Describe)*
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer 10 Mhz

Clinical Application						Mode of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							A-Mode (NEW)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140199

Device Name
VuPad

Indications for Use *(Describe)*
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer 12.5 Mhz

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	✓						

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K140199

Device Name
VuPad

Indications for Use *(Describe)*
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application. intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer 20 Mhz

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	X						

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*
K140199

Device Name
VuPad

Indications for Use *(Describe)*
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer: 35 Mhz

Clinical Application						Mode of Operation		
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	✓						

Type of Use *(Select one or both, as applicable)*

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Food and Drug Administration

Indications for Use

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510(k) Number *(if known)*
K140199

Device Name
VuPad

Indications for Use *(Describe)*
The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.

System: VuPad
Transducer 50 Mhz

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	✓						

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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